

# Certificate of Analysis

## SOLIScript® SARS-CoV-2 RT-qPCR Multiplex Assay Kit

Cat. No.

Lot No.

Pack Lot No.

**Expiry date** 

#### **Kit Components:**

- 1. Enzyme Mix 1, including:
  - SOLIScript® Reverse Transcriptase
  - RiboGrip™ RNase Inhibitor

#### 2. Enzyme Mix 2, including:

- HOT FIREPol® DNA polymerase
- Reaction buffer
- dNTPs
- 15 mM MgCl<sub>2</sub> (1x solution 3 mM)

#### 3. Primer/Probe Mix, including:

 Primers and fluorescently labelled probes for SARS-CoV-2 regions in N (FAM), E (HEX), RdRP (ROX) genes, human RNase P mRNA (Cy5).

#### 4. Positive Control:

 dsDNA Positive Control containing targets specific to the SARS-CoV-2 genomic regions targeted by the assays.

### 5. Nuclease-free Water

**Shipping conditions:** on blue ice or at 2-8°C.

**Routine Storage**: at -20°C (-28°C to -18°C) until Expiry Date. The kit can be stored at 4°C (2°C to 8°C) up to 2 months. Freeze/thaw cycles should be minimized and not exceed 20 freeze/thaws.

**Safety precautions:** Please refer to Safety Data Sheet for more information

Manufactured by Solis BioDyne in compliance with the ISO 9001 and ISO 13485 certified Quality Management System.

#### **Quality Control Assays:**

Kit components (Enzyme Mix 1, Enzyme Mix 2, Primer/Probe Mix, Positive Control, Nuclease-free Water) pass the following quality control assays:

Assay	Result
Functional testing via one-step RT-qPCR	passed
One-step RT-qPCR reproducibility	passed
DNase/RNase/Nuclease-free	passed
DNA and RNA contamination	passed

Note - Standard Quality Control Tests are performed for each individual enzyme component included in SOLIScript® SARS-CoV-2 RT-qPCR Multiplex Assay Kit and meet the designated specifications.

COA-08-85 v3

Revision date: 17.05.2023

Reason for revision: Approver's job title updated

FOR IN VITRO DIAGNOSTIC USE.

**APPROVED BY:** 

Head of Quality Management